

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

MARK GILBERT RIMBERT, individually,
and as Personal Representative of the Estates
of GILBERT JOHN RIMBERT, and
OLIVIA ACOSTA RIMBERT, deceased,

Plaintiff,

vs.

No. CIV 06-0874 JB/LFG

ELI LILLY AND COMPANY,

Defendant.

MEMORANDUM OPINION AND ORDER

THIS MATTER comes before the Court on the Plaintiff's Motion to Postpone Response to Lilly's Motion for Summary Judgment on the Basis of Preemption, filed March 20, 2008 (Doc. 57)("Motion"). The Court held a hearing on April 23, 2008. The primary issue is whether the Court should postpone briefing on Defendant Eli Lilly and Company's Motion for Summary Judgment on the Basis of Preemption, filed March 9, 2008 (Doc. 19)("Preemption Motion"), pending decisions by the Supreme Court of the United States and the United States Court of Appeals for the Tenth Circuit in allegedly similar cases. Because the Court concludes that the Supreme Court's decision may govern the legal issues in this case, and because judicial economy suggests that a postponement is appropriate, the Court will grant the motion in part and postpone Plaintiff Mark Gilbert Rimbert's response to the Preemption Motion until thirty days after the Supreme Court issues an opinion in Levine v. Wyeth, No. 2004-384, 2006 WL 3041078 (Vt. October 27, 2006), cert. granted, 128 S.Ct. 1118 (January 18, 2008)(No. 06-1249). The Court will deny, at this time, Rimbert's request that the Court postpone the case until the Tenth Circuit decides Annabel Dobbs,

individually and as Personal Representative of the Estate of Terry Dobbs, Deceased v. Wyeth Pharmaceuticals, 530 F.Supp.2d 1275 (W.D. Okla. 2008), appeal pending, (10th Cir.), without prejudice to Rimbert renewing his request after the Supreme Court rules in Levine v. Wyeth.

FACTUAL BACKGROUND

Although manufacturers may initiate labeling changes, they must submit to FDA full descriptions of all proposed changes and ordinarily await FDA approval before implementing a proposed change. 21 U.S.C. §355(b)(1)(F); 21 C.F.R. § 314.70. Throughout the lengthy regulatory history of Prozac, the FDA has, on various occasions, reviewed and considered the charge that Prozac causes or increases the risk of suicidality or violence in adults. See Defendant Eli Lilly and Company's Opposition to Plaintiff's Motion to Postpone Response to Lilly's Motion for Summary Judgment on the Basis of Preemption at 2, filed April 3, 2008 (Doc. 70)("Response"). Each time, the FDA concluded that any such proposed warnings are not based on reliable scientific evidence. See id. In the twenty years since the approval of Prozac, the FDA has not required warnings about an alleged increased risk of suicide or violence in adults. See id. As recently as August 2007, the FDA rejected such a warning regarding suicidality in adults. See id.

PROCEDURAL BACKGROUND

Rimbert asserts that Prozac causes or increases the risk of suicide or violence in adults, and that Eli Lilly should have warned of those alleged risks. See Response at 2. Accordingly, Rimbert seeks to require warnings under state law that the FDA has rejected and found to be unsupported by scientific evidence. See id. Eli Lilly contends that, in light of this conflict between Rimbert's state-law claims and the FDA-mandated labeling for Prozac, and because Eli Lilly cannot be compelled to violate federal law to avoid being held liable under state-law tort claims, federal law preempts

Rimbert's claims. See id.

Lilly has moved for summary judgment on federal-preemption grounds. See Defendant Eli Lilly and Company's Motion for Summary Judgment, filed March 9, 2008 (Doc. 19); Defendant Eli Lilly and Company's Memorandum in Support of its Motion for Summary Judgment on the Basis of Preemption, filed March 9, 2008 (Doc. 20). In this motion, Rimbert asks the Court to abate only the motion for summary judgment until the Supreme Court decides Levine v. Wyeth. See Motion at 1. The Plaintiffs also ask the Court to postpone the date for their response to the motion for summary judgment until, at a minimum, thirty days after the Supreme Court rules. See id. The Plaintiffs ask the Court to postpone the response and submission of Eli Lilly's Preemption Motion until such time as the Court best determines. See id. at 2.

The Plaintiffs' counsel, in their certificate of conference, represents that they have discussed their request with Andy See, counsel for Eli Lilly. See Motion at 2. Mr. See advises that Eli Lilly does not oppose the request to postpone the Plaintiffs' response brief until after the Court rules on this motion, but opposes the request to postpone or abate the motion for summary judgment until after the Supreme Court has decided Levine v. Wyeth. See id. In its response, Eli Lilly requests that the Court deny Rimbert's Motion to Postpone Response to Lilly's Motion for Summary Judgment on the Basis of Preemption. See Response at 1. Eli Lilly does not oppose Rimbert's request for additional time to respond to that motion. See Response at 4.

LAW REGARDING PREEMPTION

Although most of the courts that have considered the issue have found that there is no preemption, two United States District Courts in Oklahoma recently granted summary judgment in Selective Serotonin Reuptake Inhibitors ("SSRIs") suicide cases on preemption grounds. See

Annabel Dobbs, individually and as Personal Representative of the Estate of Terry Dobbs, Deceased v. Wyeth Pharmaceuticals, 530 F.Supp.2d 1275 (W.D. Okla. 2008), appeal pending, (10th Cir.); Candace Miller and George Miller v. GlaxoSmithKline, No. 03-CV-393-GKF/SAJ, 2007 WL 1662778 (N.D. Okla. June 5, 2007). Dobbs v. Wyeth involves the same class of SSRI antidepressant drugs, and the same contention that the FDA, which subsequently mandated Black Box Warnings about the risk of suicide, had considered and rejected such a warning. See 530 F.Supp.2d at 1277. In Dobbs v. Wyeth, the plaintiff

seeks damages resulting from the tragic death of her husband, Terry Dobbs, who committed suicide in December, 2002. [The p]laintiff alleges that Mr. Dobbs, who had been diagnosed with depression, committed suicide as a result of taking Effexor, a prescription antidepressant drug manufactured by [the d]efendant. [The p]laintiff contends that [the d]efendant is liable under Oklahoma common law for failing to adequately warn that Effexor could cause suicide; she asserts tort claims based on strict liability for failure to warn, negligent failure to warn, and misrepresentation.

530 F.Supp.2d at 1277. The defendant

contends that it was required to comply with the FDA regulations regarding the content of Effexor's labeling and that the FDA had concluded, as of the time of Mr. Dobbs' death in 2002, that the warning now sought by [the p]laintiff in this case was not supported by scientific evidence. [The d]efendant further argues that the FDA at that time would not have approved the warning sought by [the p]laintiff and that [the d]efendant could have been subjected to regulatory action for unlawful misbranding if it had altered its labeling to include that warning. As a result, [the d]efendant argues, the FDA regulations preempt Oklahoma's tort law regarding failure to warn.

Id. Most of the evidence in Dodds v. Wyeth concerning the FDA's awareness of this issue over the years related, not to the Effexor at issue in that case, but to Prozac. The district court stated:

In 1997, the FDA received another citizen petition regarding Prozac; it asked the FDA to require warnings indicating that people who are considered at risk for suicide and who take Prozac should be carefully observed and should also consider taking a sedative. . . . The FDA again denied the petition, discussing its previous conclusions and stating: "The agency has continued to monitor carefully reports of a possible connection between Prozac and increased suicidality. However, no credible scientific evidence has caused the agency to depart from its conclusion that

the current Prozac labeling appropriately reflects the level of concern about Prozac and suicidality.”

530 F.Supp.2d at 1282-84 (internal citation omitted). Both Dobbs v. Wyeth and Miller v. GlaxoSmithKline are on appeal to the Tenth Circuit, and Rimbart states he expects the cases to be consolidated. See Motion at 1.

Levine v. Wyeth involves a claim that defendant failed to provide adequate warnings regarding the dangers of injecting the drug Phenergan directly into a patient’s vein. See 2006 WL 3041078 at * 1. The plaintiff asserts that the defendant could have warned of the risks of adverse reactions from that delivery method and could have incorporated a proposed label change to foreclose that intravenous push injection. See id. The defendant asserts that the FDA had denied approval of a labeling-change warning of compliance of injecting Phenergan directly into a patient’s vein. See id. at 2.

In denying the motion based on federal preemption, the lower court in Levine v. Wyeth apparently concluded that the FDA did not specifically consider and reject a proposed label change to foreclose intravenous push injection and therefore held that there was no direct conflict presented between state-law failure to warn claims and the FDA regulation of the Phenergan label. See 2006 WL 3041078 at * 7. The Supreme Court of Vermont concluded: “[The d]efendant contends that in this case it was impossible to comply with both state and federal law because the FDA prohibited the use of a stronger warning with respect to IV-push administration of Phenergan. This claim is not supported by the evidence defendant presented to the trial court.” The Supreme Court of Vermont explained: “There is no evidence that the FDA intended to prohibit defendant from strengthening the Phenergan label pursuant to § 314.70(c). Thus, we cannot conclude that it was impossible for defendant to comply with its obligations under both state and federal law.” Id.

The Question Presented to the Supreme Court in the defendant's petition for certiorari is:

Whether the prescription drug labeling judgments imposed on manufacturers by the Food and Drug Administration ("FDA") pursuant to FDA's comprehensive safety and efficacy authority under the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.

available at: <http://www.supremecourtus.gov/docket/06-1249.htm>. The Supreme Court of the United States has extended the time for the petitioner to file its brief to May 26, 2008. See Docket for 06-1249, available at: <http://www.supremecourtus.gov/docket/06-1249.htm>. The time within which to file the respondent's brief on the merits is extended to and including August 1, 2008. See id. The petition for certiorari stated:

Granting this petition would enable the Court to resolve the pervasive and recurring conflict between state claims of power to regulate prescription drug labeling and the integrity of the congressionally mandated federal prescription drug labeling regime that lies at the heart of the Food and Drug Administration's ("FDA's") regulatory authority. . . . A ruling by this Court on the preemption issues presented would provide invaluable guidance to the hundreds of federal and state judges now grappling with these claims.

Petition for a Writ of Certiorari, filed March 12, 2007, 2007 WL 776723 in Levine v. Wyeth, No. 2004-384, 2006 WL 3041078 (Vt. Oct. 27, 2006), cert. granted, 128 S.Ct. 1118 (January 18, 2008)(No. 06-1249).

At the initiative of the Tenth Circuit Mediator, the first Oklahoma district court case, Dobbs v. Wyeth, is being postponed or abated until the Supreme Court rules on the preemption issue in Levine v. Wyeth. See Motion at 1. Final briefs are not due to be filed with the Supreme Court in Levine v. Wyeth until the fall of this year, see Docket for 06-1249, available at: <http://www.supremecourtus.gov/docket/06-1249.htm>, and ruling is therefore not likely to occur until sometime in late 2008 or in the first half of 2009.

ANALYSIS

The Court concludes that, under the circumstances, the wiser course of action, from a judicial economy standpoint, is to postpone the response to Eli Lilly's motion for summary judgment until the Supreme Court decides Levine v. Wyeth. The Court will thus postpone the response to the Preemption Motion until the Supreme Court issues its ruling in Levine v. Wyeth.

As Eli Lilly correctly notes, there is no guarantee that the ruling in Levine v. Wyeth will govern the preemption issues presented in this case. See Response at 1. Nevertheless, even if the Supreme Court upholds the lower court's apparent determination in Levine v. Wyeth, that a direct conflict between state law failure-to-warn claims and FDA regulation of the Phenergan label was not presented in the factual record, such a ruling could be helpful to deciding the legal issues and the facts of this case. See id. While it is true that, in this case, the FDA considered and rejected proposed warnings about alleged increased risks of suicide and violence in adults, and that under such circumstances, a ruling from the Supreme Court in Levine v. Wyeth may not govern this case, it is possible that the Supreme Court's analysis and language may be extremely helpful in resolving the motion for summary judgment in this case. See Petition for a Writ of Certiorari, filed March 12, 2007, 2007 WL 776723 in Levine v. Wyeth, No. 2004-384, 2006 WL 3041078 (Vt. October 27, 2006), cert. granted, 128 S.Ct. 1118 (January 18, 2008)(No. 06-1249)(stating that "[a] ruling by [the Supreme Court of the United States] on the preemption issues presented would provide invaluable guidance to the hundreds of federal and state judges now grappling with these claims.").

Numerous recent cases in federal court have held, under very similar factual circumstances, that failure-to-warn claims, like Rimbert's, create a conflict and are therefore preempted. See, e.g., Tucker v. SmithKline Beecham Corp., No. 1:04-cv-1748-DFH-WTL, 2007 WL 2726259 at * 1 (S.D.

Ind. September 19, 2007)(“Because the federal Food and Drug Administration (‘FDA’) requires GSK to include language in Paxil’s labeling that conflicts directly with the warning that Tucker argues was required under Indiana law, Tucker’s state law claims based on GSK’s alleged failure to warn are preempted.”); Dobbs v. Wyeth, 530 F.Supp.2d at 1289-90. (“Where the FDA has evaluated scientific evidence regarding an alleged risk associated with a drug, has considered whether that evidence warrants a labeling warning, and has expressly rejected the need for such a warning as not supported by credible evidence, a state law determination that such a warning is required creates a conflict for the manufacturer as between federal and state law, and imposes inconsistent federal and state obligations.”); Terri S. O’Neal, et al. v. SmithKline Beecham Corp., No. 06-CV-1-63-FCD-DAD, Order (E.D. Calif. January 31, 2008)(“Because plaintiffs assert claims based on a type of warning which the FDA considered and rejected due to lack of reasonable evidence during the relevant time period, this case presents the precise conflict that courts have previously identified.”). Accordingly, it may be that this case remains pending longer than Eli Lilly would like. But if Rimbert, as the plaintiff, is willing to put his case on a lengthy hold, there does not appear to be a sound reason for the Court to rush to resolve this issue without guidance from at least the Supreme Court that will forthcoming.

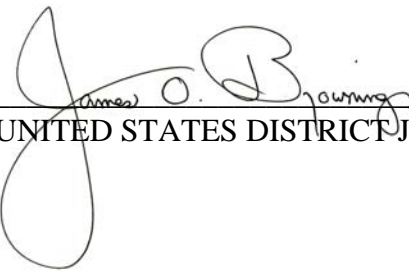
Thus, there is a strong basis to postpone the response to the Preemption Motion pending the ruling in Levine v. Wyeth. Rimbert has presented a valid reason to postpone the response to the Preemption Motion based on a future ruling that may govern this case. The actions of the Tenth Circuit’s Mediator in Dobbs v. Wyeth is an important indicator how this Court should proceed. The Court has carefully reviewed the petition for certiorari, including the question presented, Eli Lilly’s summary judgment motion, and its memorandum in support of summary judgment, and the Court

believes that resolution of Levine v. Wyeth in the Supreme Court will likely substantially assist in resolution of this case. From a standpoint of judicial economy, it makes sense to postpone the response to the Preemption Motion until the Supreme Court decides in Levine v. Wyeth.

The Court will not, at this time, postpone the response to the Preemption Motion until the Tenth Circuit decides Dobbs v. Wyeth. The Supreme Court's ruling may clearly govern the response to the Preemption Motion and allow it to proceed. In any case, the Court denies that part of the motion without prejudice to Rimbart renewing his request after the Supreme Court's decision in Levine v. Wyeth.

There is no question that postponing consideration of the Preemption Motion will likely result in a substantial delay in the resolution of the case. But if any party suffers from this delay, it will be Rimbart. Thus, the Court will postpone the response to the Preemption Motion, and the Court will grant in part the Plaintiffs' motion to postpone.

IT IS ORDERED that the Plaintiff's Motion to Postpone Response to Lilly's Motion for Summary Judgment on the Basis of Preemption is granted in part and denied in part. The Plaintiff must file his response to Defendant Eli Lilly and Company's Motion for Summary Judgment on the Basis of Preemption thirty days after the Supreme Court of the United States issues its decision in Levine v. Wyeth, No. 2004-384, 2006 WL 3041078 (Vt. October 27, 2006), cert. granted, 128 S.Ct. 1118 (January 18, 2008)(No. 06-1249). At that time, the Plaintiff may, if appropriate, renew his request that the Court further postpone resolution of the motion for summary judgment until after the United States Court of Appeals for the Tenth Circuit decides Annabel Dobbs, individually and as Personal Representative of the Estate of Terry Dobbs, Deceased v. Wyeth Pharmaceuticals, 530 F.Supp.2d 1275 (W.D. Okla. 2008), appeal pending, (10th Cir.).



UNITED STATES DISTRICT JUDGE

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